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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/955,801 | 09/19/2001 | Rajneesh Taneja | ABB01259P00210US (6842.US | 1051 |

7590 02/07/2008

TAP Pharmaceutical Products, Inc.
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| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

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|---|---|
| 02/07/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/955,801 | TANEJA ET AL. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-17 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/03/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Receipt of the Request for Continued Examination under 37 C.F.R. 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 10/31/07 and the Information Disclosure Statement (IDS) filed 12/03/07 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims: (1) The 35 U.S.C. 102(e) rejection of claims 1, 3-17 and 19-21 as being anticipated by Phillips (U.S. Pat. No. 6,489,346) has been withdrawn

Claims 1, 3-17 and 19-21 are pending in this action. Claims 1, 9 and 14 have been amended. Claims 2 and 18 have been previously cancelled. Claims 1, 3-17 and 19-21 are rejected.

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 3-17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Pat. No. 6,489,346).**

The instant invention is drawn to a solid non-enterically coated pharmaceutical formulation comprising: (a) a therapeutically effective amount of at least one acid labile pharmaceutical compound; and (b) a pharmaceutically acceptable protectant comprising (i) a water-soluble acid neutralizer; and (ii) a water-insoluble acid neutralizer, wherein the ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer is about 1:20 to about 10:1.

**Phillips ('346)** teaches a non-enteric coated solid pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent and a method for treating acid-related gastrointestinal disorders comprising administering to a patient the non-enteric coated solid pharmaceutical composition. The pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 – col. 14, line 26).

Phillips teaches that mixtures of the buffering agents can be utilized (column 13, lines 47-53). Suitable buffering agents disclosed include sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, aluminum hydroxide, aluminum hydroxide/sodium bicarbonate co-precipitate, sodium carbonate and calcium carbonate (see col. 13, line 63 – col. 14, line 14); (col. 17, lines 58-60).

The non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or an enantiomer, isomer, derivative, free base or salts thereof (see Abstract).

While Phillips does not explicitly teach the instant ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer being about 1:20 to about 10:1, the determination of suitable or effective ratios is within the level of one of ordinary skill in the art, obtained by routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Applicants have not demonstrated any superior or unexpected results, which accrue from the instant ratios claimed. The prior art vividly teaches a solid non-enterically coated proton pump inhibitor pharmaceutical composition in combination with water-soluble as well as water-insoluble acid neutralizers, that function to protect the PPI

from acid degradation and provides for the beneficially effective treatment of acid-related gastrointestinal disorders. Hence, the art suggests use of the same ingredients, being used in the same art area to achieve the same results.

The instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art, given the teachings of Phillips.

***Pertinent Art:***

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

US Patent No. 4,786,505 (Lovgren *et al.*) 11-1988

***Response to Arguments***

Applicant's arguments filed 10/31/07 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §102(e) rejection of claims 1, 3-17 and 19-21 over Phillips (US 6,489,346):**

Applicant argued, "The amendments to claims 1, 9 and 14, from which the remaining rejected claims depend, obviate the rejection because Phillips II neither teaches nor suggests a ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer being about 1:20 to about 10:1. Phillips II, instead, only teaches percentages of a water soluble acid neutralizer, a

Group IA metal bicarbonate salt, being present in the composition from about 5% to 60% (column 14, lines 18-26). Because Phillips II does not teach each and every limitation of the rejected claims, the rejection is no longer applicable. Applicants respectfully request the Office to withdraw the rejection."

Applicant's arguments have been fully considered and were found persuasive based on the amendment to the claims, which provides for the water-soluble acid neutralizer ratio: water-insoluble acid neutralizer ratio as now claimed. Accordingly, the 102(e) rejection of claims 1, 3-17 and 19-21 over Phillips (USPN 6,489,346) has been withdrawn.

- **35 U.S.C. §103(a) rejection of claims 1, 3-17 and 19-21 over Phillips (US 6,489,346):**

Applicant argued, "The amendments to claims 1, 9 and 14, from which the remaining rejected claims depend, obviate the rejection because Phillips II neither teaches nor suggests a ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer being about 1:20 to about 10:1. Phillips II, instead, only teaches percentages of a water soluble acid neutralizer, a Group IA metal bicarbonate salt, being present in the composition from about 5% to 60% (column 14, lines 18-26). Because Phillips II does not teach each and every limitation of the rejected claims, the rejection is no longer applicable. Applicants respectfully request the Office to withdraw the rejection."

Applicant's arguments have been fully considered but were not found persuasive with regards to the §103(a) rejection. The teachings of Phillips are delineated above. While Phillips does not explicitly teach the instant ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer being about 1:20 to about 10:1, the determination of suitable or effective ratios is within the level of one of ordinary skill in the art, obtained by routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, Applicants have not demonstrated any superior or unexpected results, which accrue from the instant ratios claimed. The prior art vividly teaches a solid non-enterically coated proton pump inhibitor pharmaceutical composition in combination with at least one buffering agent. The composition provides for a pharmaceutically acceptable carrier, which comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal, whereby the composition is beneficially effective for treating acid-related gastrointestinal disorders. Furthermore, while the art does not identify the specific ratios, this is solely a difference in degree and not of kind. Applicant has the burden of demonstrating what particular advantage results in the use of the specific ratios and the criticality of such. The art suggests use of the same ingredients, being used in the same art area to achieve the same results, the Applicant providing no showing of any unexpected result. The issue is whether one of ordinary skill in the art would be aware of the benefits of providing for a non-enterically coated proton pump inhibiting composition containing both a water-soluble and water-insoluble acid neutralizer to achieve therapeutically-effective results. This procedure is clearly suggested in the cited art of record.

The 35 U.S.C. §103(a) rejection has been maintained.

***Conclusion***

--No claims are allowed at this time.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1618

HUMERA N SHEIKH
PRIMARY EXAMINER

February 04, 2008

*hns*